

## CRITERIA FOR PRIOR AUTHORIZATION

Calcitonin Gene-Related Peptide (CGRP) Antagonists

**BILLING CODE TYPE** For drug coverage and provider type information, see the [KMAP Reference Codes webpage](#).

**MANUAL GUIDELINES:** All dosage forms of the following medications will require prior authorization.

Erenumab-aooe (Aimovig™)  
Fremanezumab-vfrm (Ajovy™)  
Galcanezumab-gnlm (Emgality™)

**CRITERIA FOR INITIAL APPROVAL:** (must meet all of the following)

- Patient has a diagnosis of chronic or episodic migraine
  - Chronic migraine: 15 or more headache days per month, for more than three months, which, on at least 8 days/month, has the features of migraine headache.<sup>1</sup>
  - Episodic migraine: 4 to 14 migraine days per month<sup>7</sup> (for Emgality only).
- Patient must have experienced an inadequate response after a trial of at least one agent from each medication class listed in Table 2 at a maximum tolerated dose, OR have a documented intolerance or contraindication to all preventive therapies.<sup>2</sup>
- Patient must have experienced an inadequate response to a trial of a botulinum toxin indicated for chronic migraines (trial of at least 180 days), OR have a documented intolerance or contraindication to treatment with botulinum toxins.<sup>2</sup>
  - Treatment with a botulinum toxin for chronic migraines must be discontinued prior to initiation with on a CGRP antagonist.
    - At least 90 days must have elapsed after last treatment with botulinum toxin.
- Prescriber must provide documentation of all previous medication trials. Documentation must include the medication name(s), trial date(s) and outcome(s) of the trial (i.e. inadequate response, intolerance or contraindication).
- Prescriber must attest that all medication-specific safety criteria, as defined in Table 1, is met.

**LENGTH OF APPROVAL:** 6 months

**CRITERIA FOR RENEWAL:**

- Prescriber must attest that all medication-specific safety criteria continues to be met.
- The patient must meet one of the following:
  - The patient has experienced a reduction in the number of monthly headache days compared to baseline (prior to starting treatment with the requested agent)
  - Re-initiation for chronic migraines, if reverting from other step therapies, must meet all of the following:
    - Must not have had a botulinum toxin treatment for chronic migraine in the past 90 days.
    - Must discontinue topiramate extended release for at least 30 days (90 days from last dispensing if a 90-day supply was used).

**LENGTH OF APPROVAL:** 12 months

## DRAFT PA Criteria

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.

**LENGTH OF APPROVAL (INITIAL AND RENEWAL): 6 MONTHS**

Table 1. Medication-Specific Criteria.<sup>5-7</sup>

Agents	Indication(s)	Age	Dosing Limits
Ajovy™ (fremanezumab-vfrm)	Migraine prevention	≥18	Dose must not exceed either 225 mg (1.5 mL/1 syringe) per month OR 675 mg (4.5 mL/3 syringes) every 3 months
Aimovig™ (erenumab-aooe)	Migraine prevention	≥18	70mg to 140mg subcutaneously once monthly. If using 140mg, must use the package labeled specifically for 140mg/mL.
Emgality™ (galcanezumab-gnlm)	Migraine prevention	≥18	Dose must not exceed 240 mg (2 mL/2 syringes) for initial dose and 120 mg (1 mL/1 syringe) for maintenance dosing
	Episodic cluster headache	≥18	300mg subcutaneously every month

Table 2. Prior Preventative Migraine Therapies.<sup>3</sup>

Beta-Blocking Agents	Antiepileptic Agents
Propranolol	Topiramate
Metoprolol	Valproic acid
Timolol	Divalproex

## References

1. Headache Classification Committee of the International Headache Society (IHS). The International Classification of Headache Disorders, 3rd edition. Cephalalgia. 2018;38:1-211. Available at <https://ichd-3.org/>. Accessed 6/19/19.
2. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice. Headache 2019;59:1-18. Available at <https://americanheadachesociety.org/resources/guidelines/guidelines-position-statements-evidence-assessments-and-consensus-opinions/>. Accessed on 6/19/19.
3. Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults. Neurology 2012; 78:1337-45. Available at <https://www.aan.com/Guidelines/home/GuidelineDetail/536>. Accessed 6/18/19.
4. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. Neurology 2016; 86 (19): 1818-26. Available at <https://www.aan.com/Guidelines/home/GuidelineDetail/735>. Accessed 6/18/19.
5. Ajovy (fremanezumab-vfrm) [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; Sep 2018.
6. Aimovig (erenumab-aooe) [package insert]. Thousand Oaks, CA: Amgen Inc.; Mar 2019.
7. Emgality (galcanezumab-gnlm) [package insert]. Indianapolis, IN: Eli Lilly and Company; Jun 2019.

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR

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**DATE**

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PHARMACY PROGRAM MANAGER  
DIVISION OF HEALTH CARE FINANCE  
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

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**DATE**